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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,164	06/19/2003	Sudeep M. Kumar	100390-06430	9722
22852	7590	07/17/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			TURK, NEIL N	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/600,164	Applicant(s) KUMAR ET AL.	
	Examiner Neil Turk	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 37-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 5, 6, and 12 is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/22/04, 9/16/03, 11/14/05</u> | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-36, drawn to an electrochemiluminescence cell with an electrode of platinum, iridium, or rhodium and alloys thereof, classified in class 422, subclass 52.
- II. Claims 37-58, drawn to a method of conducting an electrochemiluminescence assay at an electrode of platinum, rhodium, or iridium and alloys thereof, classified in class 73, subclass 861.12.
- III. Claims 59-61, drawn to a method of conducting an electrochemiluminescence assay comprising an electrochemiluminescence label and coreactant, classified in class 436, subclass 172.

The inventions are distinct, each from the other because of the following reasons:

Inventions II, III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP §

806.05(e)). In this case, the apparatus can be used to practice another and materially different process such as one where the process does not include electrochemiluminescence.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are unrelated because they are not disclosed as capable of use together, and have different designs in the positioning and form of the working electrode. Invention III requires using electrochemiluminescence and a coreactant as a mode of operation not included in invention II, and invention III has the effect of applying electrical energy and detecting the emitted electrochemiluminescence that is not an effect of invention II.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Rebecca McNeill on June 30th, 2006 a provisional election was made with traverse to prosecute the invention of I, claims 1-36. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 37-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

3. **Claims 5, 6, and 12** are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 5, 6, and 12 do not recite further structural limitations, but instead recite functions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 5-19** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 5, 6, and 12 do not recite the structural elements that would further limit the claims. Claims 7-11 have dependency

on these rejected claims, and as such are rejected as well. With regard to claim 12, does the working electrode have a special composition that renders it capable of inducing the ruthenium-tris-bipyridine moiety to electrochemiluminesce? This structure must be recited in the claim in order to render the claim definite. Additionally, claims 6 and 12 should recite the structural limitations which would render the claims definite for their recited functions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Niyama (5,993,740). Niyama discloses an electrochemiluminescence cell and method of its use. Niyama discloses that the cell includes working electrode 15, counter electrodes 16a, 16b, window 22 and light sensor 19 (photodetector, pmt, photodiode, lines 44-49, col. 3). Niyama discloses that the electrodes may be made of platinum, iridium, tungsten and alloys there of (lines 23-29, col. 5); examiner asserts that such a disclosure including alloys of the above metals is anticipatory to read on a first and second predetermined weight of platinum(iridium) and another element with a weight percent above zero, such that this would be inherent in an alloy. Niyama shows in figures 5A-F forms of models including a magnetic particle 40 (trapped in the chamber by way of a magnet over the working electrode, lines 62-67 col. 4), first reagent 44, TSH

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47 as the analyte in the sample, second reagent 48, reaction product 54 and TPA as the attractant in the buffer solution. Niyama also discloses that TPA (tripropylamine) is the attractant contained in the buffer solution, which is reduced upon application of a voltage so as to excite the label material and has a pH of about 7.4, and additionally the second reagent 48 has fixed to Ru(bpy)₃ (ruthenium-tris-bipyridine) as the label material (lines 44-48, col. 7; lines 65-67, col. 11; lines 1-13, col. 12, fig 5A-F).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 4-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama (5,993,740). Niyama has been discussed above. Niyama does not disclose that the second weight percent is in the range 1% to 80%. As previously stated, Niyama's disclosure to electrodes made of platinum, iridium, tungsten, and alloys

thereof anticipate a second element with a weight percent above 0%. It would have been obvious to modify the Niyama device to include an alloy of platinum with a second weight percent in the range of 1% to 80% through use of different platinum alloy compositions made from the materials disclosed by Niyama.

8. **Claims 10-19 and 33-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama in view of Wohlstadter (6,207,369). Niyama has been discussed above. Niyama does not disclose that the support for the counter electrodes is transparent and that the cell is a flow cell. Wohlstadter discloses and electrochemiluminescent cell and method of its use. Wohlstadter also discloses that commercial ECL assays are performed using a flow cell with a working and counter electrode. Wohlstadter also discloses the use of a waveform generator/potentiostat as a source of electrical energy (lines 4-12, col. 12). Wohlstadter discloses that the cell may have electrodes with field extending structures as shown in figures 19a-e, and supports for the electrodes may be of any material, including transparent materials (lines 1-10, col. 44). It would have been obvious to modify the Niyama device to include a transparent support and a flow cell such as taught by Wohlstadter in order to provide a support of a suitable material to observe reactions inside the electrochemiluminescence cell and to provide a flow cell for commercial applicability.

9. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Niyama in view of Christensen (6,036,840). Niyama has been discussed above.

Niyama does not disclose the use of rhodium or rhodium alloy electrodes. Christensen discloses a reactor for electrochemical conversion of a material. Christensen discloses that the working electrode comprises an electrically conductive material such as a metallic material selected from the group of metals including Rh (rhodium) and alloys thereof, such that the working electrode has good catalytic effect towards many kinds of electrochemical reactions with both oxidations and reductions. It would have been obvious to modify the Niyama device to include an electrode made of rhodium or a rhodium alloy such as taught by Christensen in order to provide an electrode that has good catalytic effect towards many kinds of electrochemical reactions.

10. Claims 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlstadter. Wohlstadter has been discussed above. Wohlstadter does not disclose a specific embodiment with field extending electrodes. It would have been obvious to use field extending electrodes in the electrochemiluminescent cell of Wohlstadter in order to use the electrode structures shown and suggested by Wohlstadter.

11. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being obvious over Liljestrand (6,200,531) in view of Niyama. Liljestrand discloses an apparatus for carrying out electrochemiluminescence test measurements. Liljestrand discloses that the prior art includes a flow cell (US Patent No. 5,466,416) that comprises a counter electrode 26, ECL test chamber 28, working electrode 30, transparent 32, and the flow cell 18 includes a main housing 48 formed of a transparent, chemically inert material.

Liljestrand also discloses that working electrode 30, counter electrode 26, and counter electrode 34 may consist of electrically-conductive materials such as platinum (lines 7-10, col. 2, fig. 1&2). Liljestrand further discloses that counter electrode 26 is affixed to a side of transparent block 32. With regard to claim 11, Liljestrand discloses that the counter electrode 136 may comprise a mesh or a screen and counter electrode 136 is shaped to fit a counter electrode groove in component 134 and may be "L" shaped or "T" shaped advantageously such that one "arm" of the configuration may be positioned to extend beyond component 142 to provide the provision of electrical energy (lines 58-67, col. 12; lines 1-5, col. 13). Liljestrand further discloses that the invention may also include a photodetector, e.g. a photodiode, in optical registration with the electrically-shielded window, the transparent portion of the cell wall and the working electrode (lines 33-36, col. 5). Liljestrand also discloses that a removable magnet is provided for applying a magnetic field to the working electrode (lines 37-42, col. 5). Liljestrand also discloses that electrical energy is supplied to flow cell 120 through working electrode 140 and counter electrode 136 by application of main controller 214 (waveform generator/potentiostat included in main controller 214) to cause the input fluid to electrochemiluminescence (lines 39-42, col. 17; lines 15-23, col. 18).

Liljestrand does not explicitly disclose that the electrodes are of a platinum or iridium alloy.

Niyama has been discussed above.

Niyama discloses that a material of the working electrode and a counter electrode is a platinum or iridium alloy, and use of such a material prevents wear and

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corrosion of the electrode surface caused respectively by the electrode reaction and reagents flowing over the electrode to the extent possible (lines 23-29, col. 5).

It would have been obvious to modify the Liljestrand device to include electrodes of a platinum alloy such as taught by Niyama in order to provide electrodes of a material that would prevent wear and corrosion of the electrode during electrochemiluminescence assays in the cell.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8919.

The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT


YELENA GAKH
PRIMARY EXAMINER